

# Frequently Asked Questions (FAQ)

## Virginia Department of Health (VDH) Trofile Program for Uninsured AIDS Drug Assistance Program (ADAP) Clients

Please note the Monogram Biosciences Trofile assay website includes a “Frequently Asked Questions (FAQs)” section found through the following link:

<http://www.trofileassay.com/FAQ>.

The link will direct you to three subsections for FAQs for physicians, patients, and specimen collection. Below is a summary of provider questions and specific questions submitted from local health department and private lab collection sites.

### Part One - Provider Questions:

#### 1. What is Trofile?

Trofile is a diagnostic test performed solely by Monogram Biosciences, Inc., that identifies the viral tropism of the HIV-1 virus. The type of tropism refers to which co-receptor(s) the client’s virus uses to enter the CD4+ T cell. The client’s tropism could be identified as one of the following: CCR5 (R5), CXCR4 (X4), or both (dual/mixed or D/M). “R5” tropism is considered a “positive” result.

Trofile is currently the only CLIA-validated tropism assay available for use and must be performed if a treatment-experienced client exhibits virologic failure (refer to exception criteria listed in response to Question #2) and the clinician is considering use of the drug maraviroc (Selzentry). Maraviroc (Selzentry) is a CCR5 antagonist (i.e., an entry inhibitor that blocks the CCR5 chemokine receptor on the client’s CD4+ T cell).

#### 2. What are the exception criteria for use of the Trofile Assay?

“Nucleoside reverse transcriptase inhibitor (NRTI) and non-nucleotide reverse transcriptase inhibitor (NNRTI) experienced or contraindicated with a viral load greater than 1000 copies/ml, and prior experience with one or more protease inhibitor (PIs).”

#### 3. Does the client have to be treatment-experienced before being considered for maraviroc usage?

Yes. The exception criteria for use of maraviroc include the following:

“NRTI and NNRTI experienced, or contraindicated, and prior experience with one (1) or more PIs with a positive blood test for the CCR5 co-receptor test (Trofile) within three (3) months. **Medication Exception Form required** only with the **initial** prescription. Note: The exception will be approved if a client has been taking a regimen that included this medication prior to ADAP enrollment, or accessing the medication through clinical trial or expanded access. This may be documented on the Medication Exception Form under “Reason for Exception” section of the form.

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#### 4. What is the VDH Trofile assay access program?

The VDH Trofile access program provides access to all uninsured ADAP clients to receive tropism testing via the Monogram Biosciences Trofile assay. If the medical provider determines the client experiencing virologic failure may need to use the entry inhibitor drug Maraviroc (Selzentry), the client **MUST** have a positive tropism test demonstrating that the client has an R5 tropic virus. Trofile testing is an allowable expenditure under Ryan White Part B funding. The VDH ADAP program will pay for any Trofile testing for uninsured ADAP clients.

***\*\*If the client has Medicare, Medicaid, or private insurance, that coverage **MUST** be used to obtain and pay for the Trofile test.\*\****

#### 5. What steps are involved in the Trofile program?

An overview of the program is provided on the ADAP website at:  
<http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/ADAP/support.htm/>

Basic steps include:

- a) Provider determines client is a candidate for maraviroc and Trofile testing, and downloads ADAP Medication/Lab Exception and Client Consent forms from the ADAP website. (or contacts VDH for forms). Provider completes ADAP Medication/Lab Exception Form & Client Consent Form & faxes to VDH Lab Liaison at (804) 864-8050..
- b) VDH Lab Liaison completes review and approval process for Trofile draw. Liaison contacts medical provider upon approval & instructs provider to schedule venipuncture appointment at provider selected lab collection site (from approved collection site list). Liaison notifies Monogram of approval by faxing the approved VDH Test Authorization Form.
- c) Lab collection site performs venipuncture, initial sample processing & notifies Monogram frozen samples are ready for retrieval.
- d) Monogram's courier service retrieves sample & ships to Monogram.
- e) Monogram performs the test & reports results to medical provider & to VDH ADAP program within 14 days of receipt of an acceptable sample.
- f) Upon receipt of Trofile test results, if client demonstrates a positive result (R5 tropism), VDH Lab Liaison notifies medical provider and local health department ADAP Coordinator of approval of use of maraviroc via telephone & faxed copy of approved ADAP Medication/Lab Exception Form.

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g) Provider writes prescription for Maraviroc (Selzentry) & follows usual procedure for filling ADAP prescriptions.

#### **6. What if I want to order both the Trofile test and the PhenoSense GT test from Monogram or other blood tests at the same time?**

The VDH Trofile access assay program only pays for the Trofile test, and only the Trofile test should be requested on the Monogram Biosciences Test Request Form when a Trofile test is ordered.

If the provider wishes to order additional blood tests on the client, it is suggested the provider utilize the normal procedure for ordering any other laboratory testing. Designated Trofile collection sites will only be collecting samples for the Trofile assay at the time of the Trofile venipuncture appointment.

#### **7. What happens if my client goes to a lab collection site different from where the venipuncture appointment was scheduled?**

If the client goes to a local health department not set up to perform the venipuncture, the locality will notify the VDH Lab Liaison at (804) 864-8000. The Liaison will notify the medical provider and will direct the client to the correct location.

#### **8. What happens if my client misses the venipuncture appointment?**

The provider will need to reschedule the venipuncture appointment with the laboratory collection site if using a local health department site.

#### **9. Who do I contact at VDH ADAP with questions?**

Primary contact is the VDH Lab Liaison at (804) 864-8000; secondary contact is the ADAP Coordinator at (804) 864-7919. If both lines are busy, contact (804) 864-7965 and you will be forwarded to someone who can assist you.

### **Part Two - Questions from the VDH Local Health Departments:**

#### **1. If the Lab Liaison is not in the office, is there a backup contact?**

Yes. Contact Rachel Rees, ADAP Coordinator, at (804) 864-7919.

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**2. Is there a time limit on the Trofile approval and collection process-what do we do if the doctor does everything at his/her end, but the client does not come in for the venipuncture until a month later?**

There will be fairly “tight” control on the process. After VDH has completed the initial review and approval phases, the medical provider will contact the laboratory collection site in advance to schedule the venipuncture appointment. The client will not be allowed to deviate from the appointment unless there are mitigating circumstances. If the client fails to meet the scheduled appointment, the collection site notifies the VDH Lab Liaison at (804) 864-8000. The VDH Lab Liaison will notify the medical provider that the client’s venipuncture appointment must be rescheduled. In the meantime, Monogram would have already shipped the PPT tubes to the collection facility, which should hold the tubes until such time the client’s appointment has been rescheduled.

**3. If the client forgets to bring the paperwork (test request form and client consent form), can the doctor’s office fax the forms to the lab? Can the lab complete the form once the faxed copy is sent?**

Yes, the doctor’s office may fax the signed client consent form and the Monogram Biosciences Test Request Form to the collection site. The medical provider’s office is advised to retain a photocopy of the client consent form and the test request form for their records since the provider will be sending the original versions of the forms with the client to the venipuncture appointment. Please remember since the Monogram Biosciences Test Request Form is a two-part form, if you have to work off a faxed, single page version of the form, you will need to photocopy the completed form before providing a copy to the Monogram designated courier service representative at the time of retrieval of the frozen specimen tubes. You will need to retain a copy of the test request form for your records. If the medical provider failed to complete any of the required information on the test request form, you may contact the provider’s office directly and obtain the information to complete the form.

The client consent form is also available on the ADAP website location at: <http://www.vdh.virginia.gov/epidemiology/DiseasePrevention/Programs/ADAP/support.htm> in the event the provider’s office failed to have the consent form signed or failed to maintain a copy of the signed consent form.

**4. Will a partial volume collection work if we can’t get the blood?**

You must obtain the minimum 3 ml. plasma (correlates to 6-7 ml. whole blood volume) for the Trofile assay-hence the reason both PPT tubes must be used. If the client is very difficult to draw and you are unable to collect the minimum amount, please notify the VDH Lab Liaison at (804) 864-8000 that you are unable to collect the specimen. The VDH Lab Liaison will notify the medical provider to resolve the situation when it occurs.

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**5. Once the test is positive, does the doctor then send the client to the health department for the pharmacy with the usual prescription?**

Once the test is positive (R5 tropism), the provider is able to order Maraviroc through the usual ADAP procedure. For most health departments, this means the clients take the prescription to the local health department's ADAP Coordinator, who submits to Central Pharmacy, who fills and sends back to the local health department.

For those local health departments that have their own pharmacies, the process may be handled differently depending on whether or not they stock the drug or obtain from Central Pharmacy as needed, and may assign staff to handle different aspects of the process. These health departments would follow their usual procedure for filling prescriptions for ADAP medications.

**6. Will we be responsible for collecting additional blood work not related to the Monogram Trofile Assay?**

No. The designated Trofile blood collection sites will only be responsible for collecting blood for the Trofile assay.

**7. How many tubes will Monogram send us to start the program with?**

Monogram will ship twelve (12) tubes initially upon request, and will send two (2) PPT tubes per additional request received. Please contact the VDH Lab Liaison at (804) 864-8000 if you have a Trofile client scheduled for venipuncture and have not received your PPT tubes at least three days in advance of the scheduled venipuncture.

**8. If the client went to a different local health department for ADAP eligibility determination from the local health department site to be used for the Monogram Trofile sample collection, can the eligibility information be printed from Web Vision? Does the client need to visit eligibility yearly?**

Yes, the CHS-1 can be printed from Web Vision and faxed to the VDH Lab Liaison for review to verify ADAP eligibility. The VDH Lab Liaison will confirm ADAP eligibility when the Medication/Lab Exception Form has been received from the provider to approve the Trofile assay during the initial phase of the review process.

Since the clients using the Trofile assay are part of ADAP, they will continue to go through ADAP eligibility re-determination annually. If the client's evaluation appears to be overdue, the VDH Lab Liaison will notify the local health department's ADAP Coordinator to conduct the eligibility determination.

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**9. If the provider loses the final test report, who do they call to obtain a copy of the results?**

The provider must contact Monogram Biosciences directly at 1-(800)-777-0177 or at 1-(650)-616-3638 to obtain another copy of the final test report. Since VDH was not the testing laboratory, per CLIA Requirements, the VDH ADAP program will not release the report to the provider.

**10. What do we do if the courier does not appear to have all of the packaging materials, boxes, labels with the UN# or dry ice?**

Follow the lab/courier procedure and halt the process. Contact Monogram Biosciences Logistical Support immediately at 1-(800) 777-0177 and inform them of the problem observed. Place the courier on the phone directly with the Monogram representative so Monogram may resolve the situation. Do not remove the frozen tubes from your freezer until the courier arrives with all required materials including all primary/secondary containers, absorbent material, packaging material, labeled box containing the UN3733 label, and the FedEx airbill. Also, ***DO NOT*** substitute your own courier service to package/ship the sample to Monogram.

**11. On the shipping air bill, what address is listed as the originating address?**

Monogram Biosciences' corporate address in South San Francisco is listed as both the return and the "ship to" address.

**12. If the lab experiences a power failure that affects the -20C freezer and the sample partially thaws or is "slushy" at the time the courier arrives to retrieve the sample, will the sample still be able to be shipped? Does the sample need to be completely frozen solid at the time of courier retrieval?**

The sample **MUST** be frozen **SOLID** at the time of courier retrieval. In the situation described in the question, Monogram stated the sample should be discarded and the client would have to be redrawn. Notify the VDH Lab Liaison at (804) 864-8000 if this situation should occur. The VDH Lab Liaison will notify the medical provider and Monogram and restart the process to reschedule the client for a redraw.

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**13. In the event of a power failure, if the lab has access to a dry ice supply, can the laboratory store the sample on dry ice, and if so, what is the maximum allowable time limit for storage of the sample in a sealed cooler on dry ice?**

Per Monogram Biosciences “samples should not be placed directly on dry ice. Samples can be placed in a container and then ON dry ice. The maximum allowable time limit for storage of the sample in a sealed cooler on dry ice depends on how much dry ice is used. Ten (10) pounds of dry ice in a closed shipping box last about 30 hours.”

**14. Does Monogram’s offer to place tabletop centrifuges and tabletop -20C freezers in the local health departments acting as draw sites for the Trofile assay also apply to commercial reference laboratory sites?**

Yes. Contact the VDH Lab Liaison if you need this equipment. The VDH Lab Liaison will contact Monogram Biosciences directly to process your request. Please be advised you are responsible for general maintenance. Monogram will also provide a thermometer for the freezer upon request. Monogram will also replace the units if they become inoperable. Contact Monogram Biosciences Logistical Support at 1-(800)-777-0177 should you experience any failures with the centrifuge or freezer.

Please direct any additional questions to the Laboratory Liaison,  
Phyllis Morris, at 804-864-8000 or [Phyllis.Morris@vdh.virginia.gov](mailto:Phyllis.Morris@vdh.virginia.gov)